REMARKS

Claims 1-37 have been cancelled. Claims 38-49 have been added. Claims 38-49 are pending.

Support for new claims 38-41 can be found in the specification at, *inter alia*, page 8, line 5, Example 1 at pages 15 and 16, and original claim 1. Support for new claims 42 and 43 can be found in the specification at, *inter alia*, page 8, lines 13-15 and original claims 36 and 37. Support for new claims 44 and 45 can be found in the specification at, *inter alia*, page 14, lines 10-12 and original claims 30 and 31. Support for new claims 46-49 can be found in the specification at, *inter alia*, page 14, line 27-page 15, line 13, and original claims 32-35.

No new matter has been added by the new claims; therefore, Applicants respectfully request that examination continue on the new claims.

A clean copy of all of the pending claims as they are believed to have been cancelled and added is attached to this Amendment as an appendix. The appended clean copy of all of the pending claims is provided only as a convenience to the Examiner and is not intended to be an amendment of the claims pursuant to 37 C.F.R. § 1.121.

I. Claim Objections

The Office Action has objected to claims 8-13, 21-25, 32, 34, 36, and 37 under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple claim. Claims 1-37 have been cancelled, and new claims 38-49 have been added. New claims 38-49 are not multiple dependent claims; therefore, Applicant respectfully requests the objection be withdrawn.

II. Rejections under 35 U.S.C. § 112, First Paragraph

The Office Action has rejected claims 14, 15, 26, 27, 28, 29, 36, and 37 under 35 U.S.C. § 112, first paragraph, because "the specification, while being enabling for the omega-3 fatty acids of claim 3 and particular phytosterols listed in the application does not reasonably provide enablement for all omega-3 fatty acids and sterols." The Office Action further recites that "the

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims."

Claims 1-37 have been cancelled; therefore, the rejection is moot. With respect to new claims 38-49, the application provides ample enabling disclosure for practicing invention. Example 1 of the application at pages 15 and 16 provides one aspect of the invention, which is a detailed synthetic procedure for producing stigmasterol esters of EPA and DHA. Based on the disclosure of the specification and, in particular, Example 1, one of ordinary skill in the art would not require undue experimentation to practice the invention as recited in new claim 39 and all claims dependent therefrom.

The Office Action has rejected claims 14, 15, 26, 27, 28, 29, 36, and 37 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. The Office Action asserts that "the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

Claims 1-37 have been cancelled; therefore, the rejection is moot. With respect to new claims 38-49, the written description requirement has been satisfied. Throughout the specification and, in particular, Example 1, it is clear to one of ordinary skill in the art that the inventors were indeed in possession of the invention at the time of filing as recited in new claims 38-49.

Therefore, Applicant asserts that the invention recited in new claims 38-49 satisfies all requirements of 35 U.S.C. § 112, first paragraph.

III. Rejections under 35 U.S.C. § 112, Second Paragraph

The Office Action has rejected claims 1-37 under 35 U.S.C. § 112, first paragraph. Claims 1-37 have been cancelled; therefore, the rejection is moot.

IV. Rejections under 35 U.S.C. § 102

The Office Action has made the following rejections under 35 U.S.C. § 102:

1. Claims 1-3, 7, 9, 14-16, 20, 22, and 26-28 under 35 U.S.C. § 102(a) in view of European Publication No. 897970;

2. Claims 1-3, 7, 9, 14-16, 20, 22, and 26-28 under 35 U.S.C. § 102(a) in view of European Publication No. 1004594; and

3. Claims 1-3, 9, 14-16, 20, 22, and 26-28 under 35 U.S.C. § 102(b) in view of U.S. Patent No. 5,502,045.

Claims 1-37 have been cancelled. Further, the rejections under 35 U.S.C. § 102 are not directed toward original claims 29-37, which recite a process for making sterol esters. Therefore, new claims 38-49, which are also method of making claims, are novel in view of the art.

V. Rejections under 35 U.S.C. § 103

The Office Action has rejected claims 4-6, 8, 10-13, 17-19, 21, and 23-25 under 35 U.S.C. § 103(a) in view of European Publication Nos. 897970 and 1004594. Claims 1-37 have been cancelled. Further, these rejections under 35 U.S.C. § 103 are not directed toward original claims 29-37, which recite a process for making sterol esters. Therefore, new claims 38-49, which are also method of making claims, would not have been obvious to one of ordinary skill in the art in view of European Publication Nos. 897970 and 1004594.

The Office Action also asserts that original claims 29-37 would have been obvious under 35 U.S.C. § 103 over U.S. Patent No. 5,502,045 to Miettinen in view of the journal article to Lo *et al.* In particular, the Office Action asserts that claims 27-39 are *prima facie* obvious in view of the combined teachings of Miettinen and Lo *et al.*

Claims 29-37 have been cancelled; however, for the sake of completeness, new claims 38-49 will be addressed in view of the combined teachings of Miettinen and Lo *et al.* It is well-established that, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03 (citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). Said another way, claims for an invention are not

prima facie obvious if the cited reference does not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). This is not possible when the claimed invention achieves more than what any or all of the prior art references allegedly suggest, expressly or by reasonable implication.

Here, the claimed invention as recited in new claims 38-49 includes features neither disclosed nor suggested by Miettinen or Lo *et al.* For example, new claim 38 recites, *inter alia*, the use of "an omega-3 fatty acid, wherein the omega-3 fatty acid comprises eicosapentaenoic acid 20:5ω3 (EPA), docosahexaenoic acid 22:6ω3 (DHA), an ester thereof, or a mixture thereof" to produce sterol esters.

Miettinen and Lo *et al.* do not disclose or suggest the use of eicosapentaenoic acid 20:5ω3 (EPA), docosahexaenoic acid 22:6ω3 (DHA), an ester thereof, or a mixture thereof. In the case of Miettinen, Miettinen discloses the esterification of rapeseed oil with β-sitstanol. There is no direction or motivation in Miettinen to use other fatty acids, particularly the omega-3 fatty acids EPA or DHA. Indeed, rapeseed oil does not even contain EPA and DHA. Similarly, Lo *et al.* only discloses the esterification of soybean oil with edible beef tallow. Similar to Miettinen, there is no suggestion or teaching in Lo *et al.* to use omega-3 fatty acids such as EPA or DHA, which are recited in new claims 38-49. Moreover, soybean oil also does not even contain DHA or EPA.

In the absence of any disclosure, teaching, or suggestion in Miettinen and Lo *et al.* to use the omega-3 fatty acids recited in new claims 38-49, the present invention would not have been obvious to one of ordinary skill in the art.

CONCLUSION

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

Enclosed is Credit Card Form PTO-2038 in the amount of $1,200.00 ($1,020.00 to cover the extension of time fee and $180.00 to cover the Supplemental Information Disclosure Statement). No further fee is believed to be due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Lawrence A. Villanueva, J.D., Ph.D. — Date: 2/28/05

APPENDIX

Clean Copy of All Pending Claims after Amendment (for the Examiner's convenience only)

What is claimed is:

38. A process for preparing an ester comprising the step of reacting a sterol with an omega-3 fatty acid, wherein the omega-3 fatty acid comprises eicosapentaenoic acid 20:5ω3 (EPA), docosahexaenoic acid 22:6ω3 (DHA), an ester thereof, or a mixture thereof, and the sterol comprises stigmasterol, in the presence of a base.

39. The process of claim 38, wherein the omega-3 fatty acid is eicosapentaenoic acid 20:5ω3 (EPA).

40. The process of claim 38, wherein the omega-3 fatty acid is docosahexaenoic acid 22:6ω3 (DHA).

41. The process of claim 38, wherein the omega-3 fatty acid comprises a mixture of eicosapentaenoic acid 20:5ω3 (EPA) and docosahexaenoic acid 22:6ω3 (DHA).

42. The process of claim 38, wherein the ester of the omega-3 fatty acid is a triglyceride ester.

43. The process of claim 38, wherein the ester of the omega-3 fatty acid is an ethyl ester.

44. The process of claim 38, wherein the base is a metal (C_1-C_{10}) alkoxide.

45. The process of claim 44, wherein the metal (C_1-C_{10}) is sodium methoxide.

46. The process of claim 38, further comprising the step of precipitating unreacted sterol with a suitable non-polar solvent, and filtering off the precipitated unreacted sterol to leave a filtrate.

47. The process of claim 46, wherein the non-polar solvent is hexane.

48. The process of claim 46, further comprising the step of extracting the filtrate with a suitable immiscible solvent to remove unreacted omega-3 fatty acid, or an ester thereof, from the filtrate.

49. The process of claim 48, wherein the immiscible solvent is methanol.

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